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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,247	05/25/2000	TERENCE N. DEAR	8484-081-999	3571

7590 08/09/2005

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/486,247	Applicant(s) DEAR ET AL.	
	Examiner Christian L. Fronda	Art Unit 1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because:
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: SEE CONTINUING SHEETS. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 8, 9, 16-18 and 21.
- Claim(s) withdrawn from consideration: 19, 20, 22, 23.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Art Unit: 1652

Advisory Action

Applicants' amendment and request for reconsideration filed 05/16/2005 have been considered but not entered because it raises new issues and requires the institution of new rejections. The amendment has not been entered for the following reasons stated below.

Applicants' submission of a new Sequence Listing filed 05/16/2005 is acknowledged. However, the new Sequence Listing contains substantial changes in the sequences for SEQ ID NOs: 1 and 2. Thus, the disclosure would be objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. Since the claims recite the new SEQ ID NOs: 1 and 2, then the claims would be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for introduction of new matter. Furthermore, a new search must be performed in the patent and non-patent literature for new SEQ ID NOs: 1 and 2.

Amended claims 8, 9, 16-18, and 21 would still be rejected under 35 U.S.C. 101 for lacking utility. While the examiner acknowledges applicants' arguments and assignment of the protein of SEQ ID NO: 1 encoded by the polynucleotide of SEQ ID NO: 2 as a kallikrein serine protease, the claims as written still recite broadly that the protein is a "protease-related protein" that has "homology to the kallikrein family". The claims as written do not have specific and substantial utility since there is no defined specific substrate and specific biological activity for the protein claimed as a "protease-related protein" that has "homology to the kallikrein family". Since the claims as written lack utility, then the claims would also be rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. Utilities that require or constitute carrying out further research to identify and/or reasonably confirm a specific use are not substantial and do not provide a specific benefit.

Amended claims 8, 9, 16-18, and 21 would still be rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The specification does not provide prediction, guidance, and working examples showing *in vivo* that administration of the claimed "protease-related protein" will result in reduction of normal or strong keratinization of hair. An undue amount of trial and error experimentation is required to determine this as well as the specific modes of administration (e.g., oral and intravenous administration). Thus, it cannot be predicted whether administering the claimed "protease-related protein" will result in reduction of normal or strong keratinization of hair in any patient in need of such treatment.

Since the amendment filed 05/16/2005 has not been entered, all previous rejections and objections made in the previous Office Action are maintained.

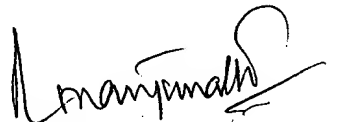
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. The

Art Unit: 1652

examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christian L Fronda
Patent Examiner
Art Unit 1652



Manjunath Rao
Primary Patent Examiner
Art Unit 1652